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(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
14 March 2002 (14.03.2002)

PCT

(10) International Publication Number
WO 02/20086 A1

(51) International Patent Classification⁷: A61N 1/05

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(21) International Application Number: PCT/US01/27688

(22) International Filing Date:
7 September 2001 (07.09.2001)

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(25) Filing Language: English

(81) Designated State (*national*): JP.

(26) Publication Language: English

(30) Priority Data:
60/230,664 7 September 2000 (07.09.2000) US
60/232,753 15 September 2000 (15.09.2000) US

(84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:

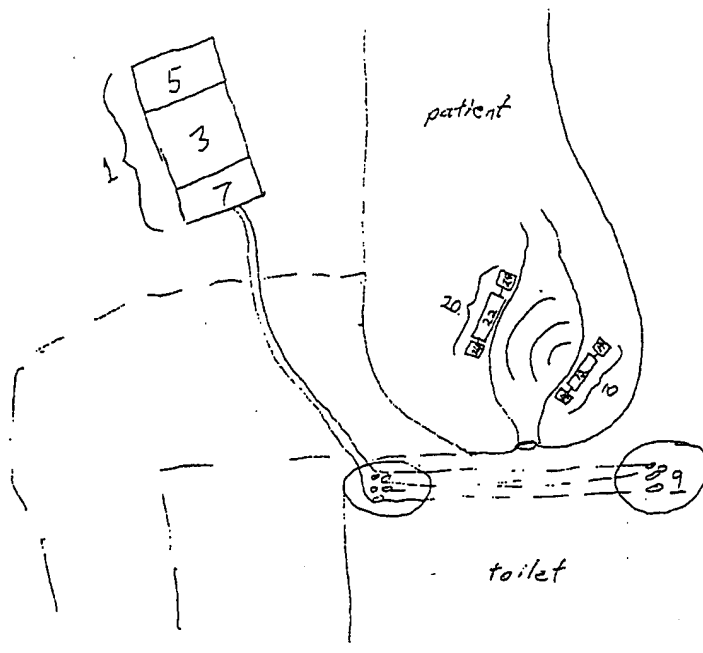
- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(54) Title: METHOD AND APPARATUS FOR CONTROL OF BOWEL FUNCTION



(57) Abstract: The invention includes microminiature electronic devices (10, 20) implanted in or around the large bowel to sense the volume and nature of rectal contents and to stimulate peristaltic contractions to empty the large bowel.

WO 02/20086 A1

METHOD AND APPARATUS FOR CONTROL OF BOWEL FUNCTION

FIELD OF THE INVENTION

[0001] This application relates to systems and methods for controlling bowel function, particularly for patients with spinal injury or diseases of the nervous system.

5 [0002] Background of the Invention

[0003] There are various surgical procedures and hydraulic implants that have been developed to provide fecal continence in cases of inadequate anal sphincter strength. Electrical stimulators for the spinal cord and sacral roots have also been used to stimulate emptying of the rectum. See previously granted patents for the
10 microstimulator implants themselves and for certain applications including therapeutic electrical stimulation (TES) to strengthen urinary and anal sphincter muscles, which are incorporated herein by reference. U.S. Patent Nos. 5,312,439, 5,697,076, 6,061,596, 5,324,316, 5,405,367, 6,051,017, 5,193,540, and 5,193,539 incorporated by reference in their entirety.

15 [0004] One of the hallmarks of social animals is the ability to control when and where they relieve themselves of solid waste products of digestion as feces. The so-called "bowel movement" is the last step in a complex series of processes whereby food is successively processed, stored and moved along successive stages of the digestive tract. These steps are normally controlled by a complex system of smooth
20 muscles, which are under the control of the autonomic nervous system. Humans with intact nervous systems have limited conscious awareness of these processes, but they do sense distension at the various loci in the gastrointestinal track and adjust their behavior accordingly. Distension produced by accumulation of fecal material in the rectum gives rise to the feeling that a bowel movement is imminent,
25 permitting the person either to go to a place where it is socially acceptable to empty the bowels or to block the expulsion of feces at least temporarily by voluntarily contracting the external anal sphincter.

[0005] If the spinal cord is defective, which may result from spinal cord injury, tumors or birth defects, then various of the steps of peristaltic motion, conscious
30 sensation, and voluntary control may be absent or abnormal. This gives rise to various problems of constipation and incontinence that interfere with the health of

such patients and their ability to participate in normal social activities. Many such patients spend an inordinate amount of time each day attempting to empty their bowels by various maneuvers and in the absence of any clear indication of whether and when this is necessary or complete.

5 SUMMARY OF THE INVENTION

[0006] The present invention therefore provides methods and apparatus for controlling bowel function. This invention includes microminiature electronic devices implanted on or around the large bowel to sense the volume and nature of rectal contents and to stimulate peristaltic contractions to empty the large bowel when it is
10 convenient for the patient to do so.

[0007] It is an object of the present invention to detect peristaltic motion and distension of the rectum.

[0008] It is a further object of the present invention to determine whether said rectal distension has resulted from accumulation of solid, liquid or gaseous material.

15 [0009] It is still a further object of the present invention to permit a patient to electrically trigger peristaltic motion upon command in order to effect defecation.

[0010] In one embodiment of the present invention, one or more microelectrical implants are injected into the walls or surgically implanted onto the serosal surface of the rectum and descending colon, where they sense motion and distension of those
20 structures and can generate electrical impulses that stimulate peristaltic contractions. External control is also included, which transmits power and command signals to the microelectrical implants and receives sensed information from them by means of an inductive coil upon which the patient sits.

25 BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 illustrates exemplary embodiments of internal and external electronic devices used in the present invention.

[0012] FIG. 2 is a block diagram of the components of both the external electronic devices and the internal electronic devices.

DETAILED DESCRIPTION OF THE INVENTION

[0013] Referring to Fig. 1, an external electronic device 1 is coupled to an inductive coil 9 upon which the patient is sitting. A first implanted electronic device 10 and a second implanted electronic device 20 are placed in the walls of the rectum or on the serosal surface of the rectum. These first and second implanted electronic devices perform both detection and triggering functions. The inductive coil 9 may be removably coupled to a toilet. It may also be removably coupled to a seat cushion or a mattress.

[0014] The first and second implanted electronic devices 10 and 20 each comprise a hermetically sealed capsule 12 and 22 in which electronic circuitry is located. Attached to the hermetically sealed capsules 12 and 22 are two electrodes 14 and 24. The electronic circuitry may include an inductive coil, power storage capacitor, and integrated circuit for performing various functions as detailed below and illustrated schematically in Fig. 2.

[0015] The external electronic device 1 transmits power and command signals to implanted electronic devices 10 and 20 by creating a modulated radio frequency (RF) field on the inductive coil 9. The modulated radio frequency field may be created using a variant of a Class E power oscillator 7 called "suspended carrier transmission". In this scheme, a very high Q resonant circuit ($Q > 100$) consisting of inductive coil 9 and a tuning capacitor can be energized to a high level of inductive field strength while drawing only a small current from a power supply. When the peak sustained oscillations have been achieved in inductive coil 9, the carrier may be 100% modulated in fewer than four carrier cycles by opening a switch in the circuit between the tuning capacitor and the coil at precisely the instant when the current through the coil is zero and the voltage on the capacitor is maximal. The carrier can be reinstated rapidly and with minimal energy loss by closing the switch. The number of cycles in which the carrier is on or off can be used to encode digital data for the purpose of controlling the implanted electronic devices 10 and 20. When the switch is open and the carrier is off, inductive coil 9 can be used as a high impedance antenna to detect outgoing emissions that encode information from implanted electronic devices 10 and 20.

[0016] The implanted electronic devices 10 and 20 may be used as a pair to perform different types of measurements. In one embodiment, the implanted electronic devices measure physical distension of the rectum. The implanted electronic device 10 emits a short burst of RF energy upon command from external electronic means 1, at a time at which the suspended carrier is in the off state. The implanted electronic device 20 detects the strength of the short burst of RF energy emitted by the implanted electronic device 10, which depends on the physical orientation and distance between the two implanted electronic devices. By locating the implanted electronic devices on opposite sides of the rectum, the strength of the RF coupling between the two devices will reflect distension of the rectum.

[0017] In another embodiment, the implanted electronic devices measure the electrical resistance of the material in the rectum. The implanted electronic device 10 emits a brief electrical current from its two electrodes 14. The implanted electronic device 20 detects the strength of the electrical field created in the adjacent tissues via its two electrodes 24 which are connected to an amplifier and a digitizer. The field strength depends on the dimensions and electrical conductivity of the material separating the two implanted electronic devices. Solid fecal material has an electrical conductivity that is midway between liquids (high electrical conductivity) and gases (low electrical conductivity).

[0018] The results of the two measurements described in the embodiments above are transmitted to the external electronic controller 1 which uses the information about distance and electrical coupling to infer both the amount and the nature of the rectal distension. This information can be presented to the patient through an interface 5, whereupon the patient decides if and when it is necessary to empty the rectum. In the event that the patient decides to empty the bowels, this is conveyed through interface 5 to a controller 3 which transmits commands to one or both of the implanted electronic devices that cause them to emit electrical current pulses sufficiently strong to trigger peristaltic contractions of the rectum.

[0019] The implanted electrical devices 10 and 20 may also include an electrical stimulator implanted into the tissues of rectoanal region to facilitate the emptying of the rectum. The implanted electrical devices 10 and 20 may also include an electrical stimulator that activates a plurality of preganglionic parasympathetic neurons to trigger defecation. The implanted electrical devices 10 and 20 may also include an

electrical stimulator that activates a plurality of perianal cutaneous afferents that activate spinal reflexes to trigger defecation.

[0020] Figure 2 provides a more complete block diagram of the electronic functions performed by circuitry within the external and implanted components in order to support the operations described above. In particular, it depicts an embodiment in which a single type of implant can perform a multitude of functions upon command from the external components. It will be obvious to one skilled in the art that these electronic functions may be divided into two or more types of more specialized implants.

[0021] Referring to Fig. 2, the external components 1 may be subdivided into functional blocks as follows. The user interface 5 provides a display whereby the user can see the results of the measurements in a simplified form upon which he/she can base decisions about self care and control. The user can instruct the system to begin or terminate self-care functions such as stimulating the evacuation of the rectum.

[0022] The controller 3 includes all digital circuitry required to operate the remainder of the system, including storage devices that are loaded with and retain information specific to the patient and the implanted components, such as calibrations for the sensors and stimulus parameters required to perform self-care functions.

[0023] Power can be provided by AC/DC converter, batteries, or any other suitable device.

[0024] Communication with the implanted electronic devices is achieved by inductive coupling between the external inductive coil 9 and inductive coils contained within each implant.

[0025] A driver 7 uses Class E circuitry to create a sufficiently high field strength of the RF carrier signal produced in external inductive coil 9 so that the voltage generated in each implant's inductive coil is sufficient to power the electronic circuitry in that implant. A tuning capacitor plus the external inductive coil 9 form a resonantly tuned tank circuit with a high Q.

[0026] An encoder formats the digital command information from the controller 3 to each implant so that it can be applied to the driver 7 in order to modulate the RF carrier signal so as to convey that command information to the implants.

5 [0027] After commanding an implant to transmit out sensor data, the controller 3 must stop the transmission of RF power from the external inductive coil 9 by opening an electronic switch in the tank circuit at approximately the phase in the RF oscillation when the field strength in inductive coil 9 passes through zero. This causes inductive coil 9 to act like a high impedance antenna for the much weaker RF oscillations produced by the implant that is transmitting said sensor data by
10 amplitude modulation of this outgoing RF signal.

[0028] A detector circuit amplifies and conditions the outgoing RF signal as picked up by the inductive coil 9 acting as an antenna.

[0029] A decoder circuit converts the amplitude fluctuations in the outgoing RF signal into digital data representing the sensor data, which is then processed by the
15 controller 3.

[0030] Referring to Figure 2, the implanted electronic devices 10 and 20 may each be subdivided in functional blocks as follows. The implant electronic circuitry 10 and 20 is contained within the hermetically sealed capsule 12 and 22 that protects it from moisture. It is connected to a pair of electrodes 14 and 24 affixed outside the
20 package so as to make electrical contact with the body tissues.

[0031] An inductive coil and capacitance produces a resonant circuit tuned to the RF carrier frequency, wherein said capacitance includes self-capacitance of the coil windings plus any additional capacitance required for tuning. In its idling state, the resonant circuit is connected to the receiver circuitry, which extracts electrical power
25 from the received RF carrier signal and directs it to a power circuit and to a data circuit. The power circuit converts the RF power to a filtered and regulated DC voltage that powers the other circuitry. The data circuit detects modulation of the RF carrier signal and converts these modulations to digital data that controls the operation of the remainder of the implant circuitry (not all data effects are shown
30 schematically).

[0032] One primary role for the received digital data is to specify the strength and timing of electrical pulses emitted through electrodes 14 and 24, as controlled by the

stimulator function. When stimulation pulses are not being emitted but an RF carrier signal is being received, power extracted from the carrier is stored by on the electrodes themselves by the charger. The Ta electrode is pre-anodized to approximately four times the maximal DC voltage produced by the power and
5 charger circuitry so that it acts as an electrolytic storage capacitor with respect to the electrically conductive bodily fluids surrounding the electrode. This permits relatively large amounts of power to be stored and released in the form of intense, brief, intermittent stimulation pulses.

[0033] The electrodes 14 and 24 can also be disconnected from both the charger
10 and stimulator circuitry and connected to an amplifier circuit that amplifies and conditions potentials present on the electrodes. Thus, when one implant is generating a stimulus pulse, another implant can measure the strength of the potential field created in its vicinity by the stimulus pulse, the field strength of which will depend on the nature and thickness of the tissue intervening between the two
15 implants.

[0034] The amplified signal from the electrodes or a signal from another sensor that may be included is switched to the digitizer which produces digital data corresponding to the amplitude of the sensor signal. The digitized sensor data is used to modulate a transmitter which causes the resonant circuit to emit an outgoing
20 RF telemetry signal that is received by the external inductive coil and its related detector and decoder circuitry. During this transmission, the external circuitry stops transmitting its RF carrier signal.

[0035] When one implant is generating an outgoing RF telemetry signal, one or more other implants in its vicinity can be commanded to act as sensors of the
25 strength of the RF signal in their vicinity. The RF signal picked up by an implant that is functioning as an RF field sensor is amplified and conditioned by the detector circuit and conveyed to the digitizer for later transmission outward.

[0036] It is to be understood that other embodiments may be utilized and structural and functional changes may be made without departing from the respective scope of
30 the present invention. The attached description of exemplary and anticipated embodiments of the invention have been presented for the purposes of illustration and description. They are not intended to be exhaustive or to limit the invention to

the precise forms disclosed. Many modifications and variations are possible in light of the teachings herein.

WE CLAIM:

1. A system for controlling bowel function, the system comprising:
a first implanted electronic device to detect distension of the rectum;
a second implanted electronic device to trigger peristaltic evacuation of the
5 bowel; and
an external electronic device coupled to an inductive coil.

2. The system of claim 1 wherein the first and second implanted
electronic devices measure the distance between the first and second implanted
electronic devices by emitting an electromagnetic field and measuring the strength of
10 the electromagnetic field.

3. The system of claim 2 wherein the first and second implanted
electronic devices measure the electrical coupling provided by a material between
the first and second implanted electronic devices by emitting an electrical current
and measuring the strength of a potential field.

4. The system of claim 3 wherein the external electronic device computes
15 a electrical resistance of the material between the first and second implanted
electronic devices.

5. The system of claim 1 further comprising an electrical stimulator
implanted in a rectoanal region.

6. The system of claim 5 further comprising an electrical stimulator
20 activating a plurality of preganglionic parasympathetic neurons to trigger defecation.

7. The system of claim 5 further comprising an electrical stimulator
activating a plurality of perianal cutaneous afferents to activate spinal reflexes to
result in defecation.

8. The system of claim 5 wherein the external electronic device includes
25 an interface to permit activation of the electrical stimulator.

9. The system of claim 1 wherein the first and second implanted
electronic devices receive power and command signals by an electromagnetic
coupling to the external electronic device.

10. The system of claim 9 wherein a class E electronic power oscillator that is 100% modulated in fewer than four carrier cycles electromagnetically couples the implanted electronic devices and the external electronic device.

11. The system of claim 9 wherein the inductive coil electromagnetically
5 couples the implanted electronic devices and the external electronic device.

12. The system of claim 1 wherein the implanted electronic device communicates with the inductive coil.

13. The system of claim 12 wherein the inductive coil is removably coupled to a toilet.

10 14. The system of claim 12 wherein the inductive coil is removably coupled to a seat cushion.

15. The system of claim 12 wherein the inductive coil is removably coupled to a mattress.

16. A method for controlling bowel function, comprising:
15 implanting at least one microelectrical device in the rectal wall so as to stimulate peristaltic contractions; and
stimulating the microelectrical device in order to empty the bowel.

17. A method for determining the state of material in the rectum by measuring the electrical resistance of the material in the rectum, the method
20 comprising:

implanting first and second microelectrical devices in the rectal walls so as to stimulate peristaltic contractions;
emitting a brief electrical current from the first microelectrical device; and
measuring the strength of the electrical field at the second microelectrical
25 device.

18. A method for determining the state of material in the rectum by measuring the electrical resistance of the material in the rectum, the method comprising:

implanting first and second microelectrical devices in the rectal walls;

emitting a brief electrical current from the first microelectrical device;
measuring the strength of the electrical field at the second microelectrical device; and

transmitting the measurement recorded at the second microelectrical device
5 to an external controller which uses information about the distance and electrical coupling of the first and second microelectronic devices to infer the resistance and nature of the material in the rectum.

19. A method for measuring physical distension of the rectum, the method comprising:

10. implanting first and second microelectrical devices in the rectal walls so as to stimulate peristaltic contractions;

emitting a short burst of RF energy from the first microelectrical device; and
measuring the strength of the short burst of RF energy at the second microelectrical device.

15 20. A method for measuring physical distension of the rectum, the method comprising:

implanting first and second microelectrical devices in the rectal walls so as to stimulate peristaltic contractions;

emitting a short burst of RF energy from the first microelectrical device;
20 measuring the strength of the short burst of RF energy at the second microelectrical device; and

transmitting the measurement recorded at the second microelectrical device to an external controller which uses information about the distance and electrical coupling of the first and second microelectronic devices to infer the amount and
25 nature of the rectal distention.

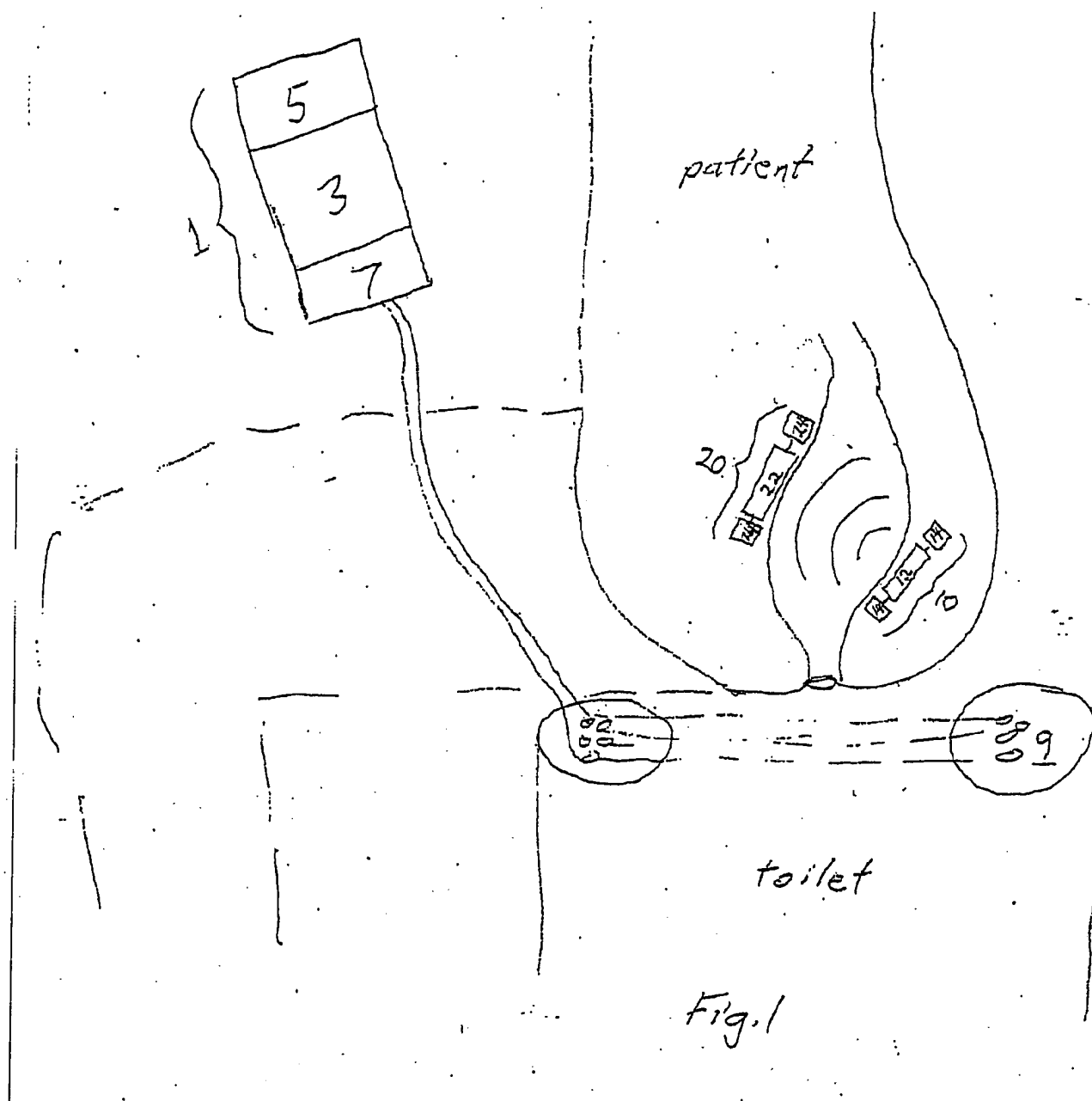
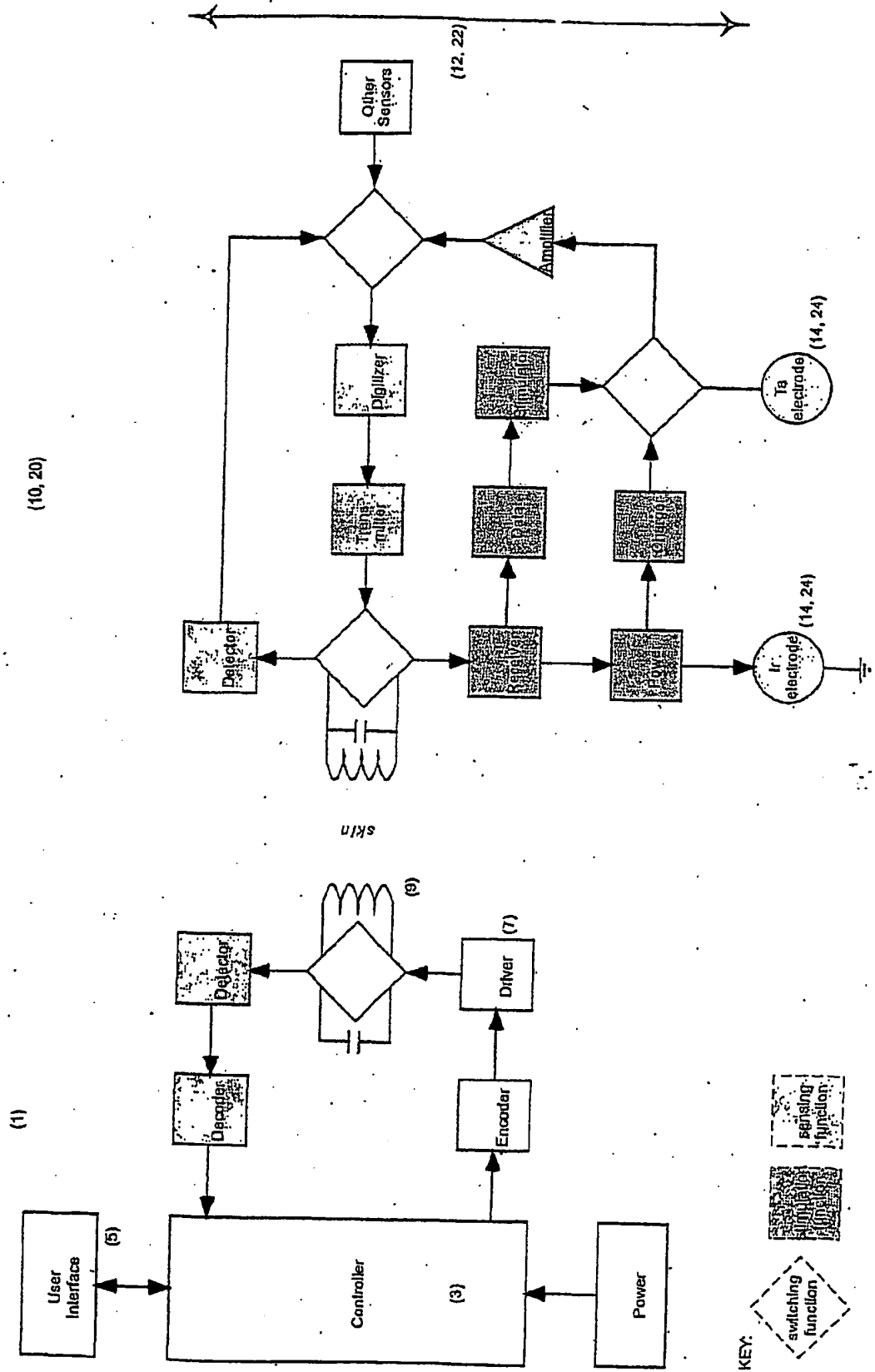


Fig. 2
System Block Diagram

External Components

Implants



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/27688

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61N 1/05

US CL :607/40

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/40

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US 6,238,423 B (Bardy) 29 May 2001, see entire document.	16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search

14 NOVEMBER 2001

Date of mailing of the international search report

08 FEB 2002

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